



EXHIBIT B

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CASE INFORMATION**CV-21-952213 BRIAN CHERKALA, ET AL. vs. LIVANOVA DEUTSCHLAND GMBH, ET AL.****Docket Information**

Filing Date	Docket Party	Docket Type	Docket Description	View Image
08/26/2021	P	MO	MOTION FILED FOR PLAINTIFF(S) BRIAN CHERKALA(P1) and YVONNE CHERKALA(P2) DENNIS R. LANSDOWNE 0026036 MOTION FOR RELIEF PURSUANT TO CIV. R. 10(D)(2)(B) (FILED CONCURRENTLY WITH PLAINTIFFS' COMPLAINT)	
08/26/2021	N/A	SF	JUDGE WILLIAM F. B. VODREY ASSIGNED (RANDOM)	
08/26/2021	P1	SF	LEGAL RESEARCH	
08/26/2021	P1	SF	LEGAL NEWS	
08/26/2021	P1	SF	LEGAL AID	
08/26/2021	P1	SF	COURT SPECIAL PROJECTS FUND	
08/26/2021	P1	SF	COMPUTER FEE	
08/26/2021	P1	SF	CLERK'S FEE	
08/26/2021	P1	SF	DEPOSIT AMOUNT PAID SPANGENBERG, SHIBLEY & LIBER, L.L.P.	
08/26/2021	N/A	SF	CASE FILED: COMPLAINT	

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Cleveland, Ohio 44113

Court of Common Pleas

MOTION FOR...
August 26, 2021 11:20

By: DENNIS R. LANSDOWNE 0026036

Confirmation Nbr. 2336456

BRIAN CHERKALA, ET AL.

CV 21 952213

vs.

Judge: WILLIAM F. B. VODREY

LIVANOVA DEUTSCHLAND GMBH, ET AL.

Pages Filed: 27

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

BRIAN CHERKALA, et al.)	CASE NO. CV 21 952213
)	
Plaintiffs)	JUDGE VODREY
)	
vs.)	
)	<u>MOTION FOR RELIEF PURSUANT TO</u>
LivaNova Deutschland, GmbH, et al.)	<u>CIV.R. 10(D)(2)(b) [Filed concurrently</u>
)	<u>with Plaintiffs' Complaint]</u>
Defendants)	
)	

Plaintiffs Brian and Yvonne Cherkala, by and through counsel, hereby submit this Motion for Relief Under Civ.R. 10(D)(2)(b).

I. INTRODUCTION

This lawsuit against Defendant Cleveland Clinic Foundation (“CCF”) does not allege “medical claims” under R.C. 2305.113 because the wrongful conduct alleged in the Complaint does not arise from Plaintiff Brian Cherkala’s medical care or treatment. Instead, the negligent acts and omissions are believed to have occurred **before** the open-heart surgery he received and involved either: 1) nonmedical CCF technicians’ failure to properly disinfect the heater-cooler device that later introduced harmful bacteria to his body; or 2) CCF administrators’ failure to replace the defective heater-cooler or train and supervise the nonmedical technicians tasked with disinfecting the device. The negligence of these nonmedical actors, none of whom are believed to have been Mr. Cherkala’s caregivers, does not qualify as a “medical claim” under Ohio law, and therefore an affidavit of merit is not required.

However, if their claims against CCF are deemed to be medical claims, Plaintiffs request an extension of time to file an affidavit of merit pursuant to Civ.R. 10(D)(2)(b).

Good cause exists to grant such an extension under Civ.R. 10(D)(2)(c) because Plaintiffs are not in possession, despite diligent efforts, of documents that would allow a medical doctor (or other qualified expert) to render an expert opinion meeting the requirements of Evid.R. 702 that CCF breached a medical standard of care. Indeed, to date no evidence has come to light that would show that the claims against CCF do constitute medical claims under R.C. 2305.113. Plaintiffs request an extension of the period in which to file an affidavit of merit until such time as the facts demonstrate medical claims exist.

As such, and for the reasons explained in greater detail below, an affidavit of merit is not required in this action. In the alternative, Plaintiffs request an extension of time to file an affidavit of merit based upon good cause shown.

II. FACTUAL BACKGROUND

A. Allegations in the Complaint

The lawsuit arises from the negligent design, manufacture, warning, and maintenance of a Stockert 3T Heater-Cooler device that was later utilized in Plaintiff Brian Cherkala's open-heart surgery. Complaint at ¶¶ 1, 47-86.

The 3T Heater-Cooler regulates blood temperature during cardiothoracic surgery by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. The water tanks and other areas through which water passes aerosolize a vapor containing non tuberculosis mycobacterium (NTM), which exits out of the device and is pushed into the ambient air of the operating room through the System's exhaust fan. If placed in the operating room, contaminated vapor from the 3T System directly enters the sterile surgical field and the patient's open body. Complaint

at ¶¶ 16-17. If NTM enters a patient's open chest cavity during surgery, it can colonize and infect the patient's body, causing severe illness. *Id.* at ¶¶ 12-15.

After CCF learned that these heater-coolers could introduce harmful NTM bacteria into the bodies of patients, they had two choices: replace the units or diligently disinfect them. Complaint at ¶¶ 79-86. The cleaning and disinfection of the heater-cooler units is believed to have been performed by nonmedical technicians or engineers. *Id.* at 81.

Plaintiffs have no documentary evidence on which an expert could rely that shows what, if anything, was done to clean or disinfect the heater-cooler units, when any cleaning or disinfection was attempted, or who attempted it. Given this dearth of evidence at this time, Plaintiffs are unable to produce an expert affidavit regarding standard of care. Nevertheless, NTM entered Mr. Cherkala's chest cavity during his surgery, colonized, and led to permanent and debilitating illness. *Id.* at 86. Plaintiffs therefore allege that CCF negligently maintained and cleaned the units, negligently failed to train and supervise the nonmedical personnel responsible for the maintenance and cleaning, and/or negligently failed to replace the defective units. *Id.* at ¶¶ 79-86.

B. Plaintiffs' attempts to obtain necessary documents from CCF

On September 15, 2020, Plaintiffs issued a subpoena to CCF in connection with their case filed against the manufacturer Defendants in Federal Court. See Exhibit 1. The case was transferred to MDL 2816, currently pending in the Middle District of Pennsylvania. The subpoena sought, among other things, documents (mostly non-medical records) relating to: 1) the maintenance, cleaning, and disinfection of the heater-cooler used during Mr. Cherkala's surgery; 2) modifications to CCF's heater-cooler devices, including replacement of PVC tubing; 3) training, information, education, and/or

certification provided to CCF employees by the manufacturer Defendants; and 4) CCF policies and procedures relating to the cleaning and disinfection of heater-cooler devices.

On October 8, 2020, CCF responded to the subpoena and produced 1,036 pages of documentation, comprised mostly of communications between the manufacturer Defendant entities and CCF. However, CCF maintained many objections to the requests, and did not produce documents evidencing the maintenance, cleaning, and disinfection of the heater-cooler unit used during Mr. Cherkala's surgery, modifications to its heater-cooler units, or its own policies, procedures, and protocols relating to the cleaning and disinfection of its heater-cooler units. CCF indicated it was only producing the documents in "good faith." See **Exhibit 2**.

On March 5, 2021, Plaintiffs' counsel wrote CCF and detailed fifteen categories which appeared to have been ignored or from which documents appeared to be missing. **Exhibit 3**. Two months later, after having received no reply, Plaintiffs' counsel followed up his letter with an email. **Exhibit 4**. On May 24, 2021, CCF responded that it produced all non-privileged documents "pertinent to Mr. Cherkala," but also emphasized that "discovery like this is supposed to be stayed in the MDL," and that Plaintiffs should have "everything needed to participate in the MDL process... including the MDL settlement program." *Id.* On June 22, 2021, Plaintiffs' counsel responded that he needed documents showing that CCF cleaned and disinfected the heater-coolers to respond to the manufacturer Defendants' allegations that CCF failed to follow their cleaning and disinfection instructions, as well as all of the other documents identified in his prior letter. **Exhibit 5**. Since that letter, CCF has failed to further respond or produce any documentation.

III. **PLAINTIFFS' CLAIMS ARE NOT MEDICAL CLAIMS UNDER R.C. 2305.113**

The claims brought against CCF in the Complaint are not “medical claims” because the negligent conduct did not “arise[] out of” Mr. Cherkala’s “medical diagnosis, care, or treatment.” R.C. 2305.113(E)(3) Furthermore, for negligent training and supervision claims to be deemed “medical claims” they must relate to a “caregiver providing medical diagnosis, care, or treatment;” here, they do not. R.C. 2305.113(E)(3)(c)(ii).

“[N]ot all injuries that a patient might sustain in a hospital or nursing home setting are necessarily “medical claims.” *Balascoe v. St. Elizabeth Hosp. Med. Ctr.*, 110 Ohio App.3d 83, 85, 673 N.E.2d 651 (7th Dist.1996).” *Haskins v. 7112 Columbia, Inc.*, 7th Dist. No. 13 MA 100, 2014-Ohio-4154, 20 N.E.3d 287, ¶ 16 (citations in original.)

To be a medical claim, a claim must arise from the plaintiff’s “medical diagnosis, care, or treatment.” See 2305.113(E)(3). To determine if a claim “arises” from these specific and narrow circumstances, the Ohio Supreme Court ruled that the law requires an examination of whether the actor’s conduct “directly involved” the “identification and alleviation of a physical or mental illness, disease, or defect.” See *Browning v. Burt*, 66 Ohio St.3d 544, 557 (1993).

Here, Mr. Cherkala has not alleged that CCF’s misconduct “directly involved” the identification and alleviation of his illnesses. Instead, CCF’s misconduct occurred well before his surgery and did not specifically relate to him as a patient. Mr. Cherkala alleges that, before his surgery, CCF failed to maintain, disinfect, or replace the defective heater-cooler device or to adequately train and supervise the nonmedical technical personnel who were tasked with maintaining or disinfecting the device. Complaint at ¶¶ 79-86.

In *Browning, supra*, the Ohio Supreme Court found that a claim for negligent credentialing of a doctor who later committed medical malpractice was **not** a medical claim subject to the statute. 66 Ohio St.3d at 557. “Claims against a hospital for negligent credentialing do not arise out of the medical diagnosis, care, or treatment of a person. Negligent credentialing claims arise out of the *hospital’s* failure to satisfy its independent duty to grant and continue staff privileges only to competent physicians.” *Id.* at 557.

Browning is instructive because the Court defined “medical diagnosis, care, or treatment” and provided guidance for interpreting R.C. 2305.113. *Browning, supra*, 66 Ohio St.3d at 557. “The terms ‘medical diagnosis’ and ‘treatment’ are terms of art having a specific and particular meaning relating to the identification and alleviation of a physical or mental illness, disease, or defect.” *Id.* The term ‘care’ “should not be broadly interpreted.” *Id.* To be a medical claim, the actor’s conduct must “directly involve” the identification and alleviation of a physical or mental illness, disease, or defect. *Id.*

The Court concluded that administrative negligence in credentialing a doctor did not “directly involve” identifying or alleviating any physical or mental illnesses of the plaintiff. 66 Ohio St.3d at 557. It found this to be true even though such negligence “may ultimately lead to an act of medical malpractice by the incompetent physician.” *Browning, supra*, 66 Ohio St.3d at 557. “The physician’s ultimate act of medical malpractice is factually and legally severable and distinct from the hospital’s acts or omissions in negligently credentialing him or her...” *Id.*

Despite the General Assembly’s later amendment of the law to specifically encompass negligent credentialing, the general “rule of *Browning*” still stands: “The rule of *Browning* requires proof that the **actor’s conduct** related to the identification and

alleviation of a physical or mental illness, disease, or defect in order to constitute the basis of a medical claim.” *Jett v. Interim Healthcare*, 2nd Dist. Montgomery No. 22727, 2008-Ohio-6332, ¶ 44. (emphasis added.)

If a defendant’s conduct did not directly involve the identification and alleviation of an illness, a plaintiff’s claim is not a “medical claim.” In *Summers v. Midwest Allergy Assoc., Inc.*, 10th Dist. Franklin No. 02AP-280, 2002-Ohio-7357, ¶ 34, a cabinet came loose from the wall in a hospital and fell on the plaintiff while she was undergoing a physician-ordered treatment. The Court found that there was no “medical employee responsible for exercising professional expertise that was either responsible for, or could have eliminated, her injury.” *Id.* Instead, the claim arose from the hospital’s failure to maintain its premises and was not a medical claim. *Id.* See also *Balascoe v. St. Elizabeth Hospital Med. Ctr.* (1996), 110 Ohio App.3d 83, 673 N.E.2d 651, [the plaintiff was an emergency room patient of the defendant hospital and she slipped and fell on a piece of plastic left on the floor, suffering personal injuries; the claims were not medical claims]; *Tayerle v. Hergenroeder* (Dec. 10, 1999), Geauga App. No. 98-G-2195, [plaintiff went to the physician’s office to receive physical therapy after knee surgery and fell leaving the office; not a medical claim.]

In *Boltenhouse v. Ohio State Univ. Hosp.*, 540 N.E.2d 761, 762-763 (Ct.of Cl.1989), the plaintiff’s decedent was addicted to pain medication and was treating at the defendant hospital. The decedent was allowed to purchase a large amount of Tylenol at the hospital gift shop, and overdosed. There, the “[p]laintiff did not claim that there was any medical diagnosis, care, or treatment which was unacceptable. Rather, the critical issue pertains to whether defendant was negligent in selling drugs to said patient at the

defendant's gift shop without physician approval.” *Id.* “The court views this action as a claim of negligence as to hospital administration, and as such R.C. 2305.11 and Evid.R. 601(D) are not applicable.” *Id.*

Here, Mr. Cherkala’s allegations and claims do not “directly involve” the identification and alleviation of his illnesses. The errors were made by the hospital administration, through failing to replace equipment, order disinfection of equipment, or train and supervise the nonmedical technicians and engineers in the proper disinfection of that equipment. Alternatively, the errors were made by the nonmedical technicians and engineers in improperly disinfecting the heater-coolers. These are not medical errors made during the diagnosis, care, or treatment of Mr. Cherkala. In fact, these errors occurred independent of Mr. Cherkala’s open-heart surgery altogether. In this case, the hospital administration and technical staff failed “to satisfy [their] independent duty” to maintain the heater-coolers. *Browning, supra*, 66 Ohio St.3d 544 at 557.

Like the plaintiffs’ claims in *Summers, Balascoe, Tayerle, and Boltenhouse, supra*, Mr. Cherkala’s claims are demonstrably distinct and severable from any sort of “medical negligence” claim that, in theory, could arise from an open-heart surgery and be brought against a doctor or nurse, like the retention of a foreign body, for example. Because Mr. Cherkala’s claims¹ are not medical claims, no affidavit of merit is required.

¹ If Mr. Cherkala’s claims against CCF are not medical claims, neither is Mrs. Cherkala’s derivative claim for loss of consortium.

A. Mr. Cherkala's Claims Do Not Result from "Medical Care" or Involve "Caregivers"

R.C. 2305.113(E)(3)(c) sets forth additional criteria under which a claim could be labeled a "medical claim." Those criteria are not met here and therefore no affidavit of merit is required.

Subsection (E)(3) of the statute expands on what constitutes a "medical claim," including:

(c) Claims that arise out of the medical diagnosis, care, or treatment of any person... and... either of the following applies: (i) the claim results from ***acts or omissions in providing medical care***. (ii) the claim results from the hiring, training, supervision, retention, or termination of ***caregivers providing medical, diagnosis, care, or treatment***.

R.C. 2305.113(E)(3)(c). (emphasis added.)

The relevant questions are whether CCF's negligence occurred during the provision of "medical care" to trigger R.C. 2305.113(E)(3)(c)(i); and whether the nonmedical technicians and engineers qualify as "caregivers" under subsection (ii). The answer to both is no.

First, as explained above, Mr. Cherkala's claims do not result from CCF's "acts or omissions in providing medical care." R.C. 2305.113(E)(3)(c)(i). In proximately causing Mr. Cherkala's injuries, CCF and its nonmedical employees were not attempting to "identify or alleviate" any illness specific to him, to use the Ohio Supreme Court's definition of "medical care." *Browning, supra*, 66 Ohio St.3d at 557. Their wrongful conduct surrounded the maintenance of heater-cooler devices generally and occurred independent of Mr. Cherkala's surgery. Therefore, Mr. Cherkala's claims did not result

from CCF's "acts or omissions in providing [him] medical care," and R.C. 2305.113(E)(3)(c)(i) does not apply.

Second, Mr. Cherkala's claims of negligent training and supervision are not medical claims under R.C. 2305.113(E)(3)(c)(ii), either. Subsection (ii) applies only to negligent training and supervision of "caregivers providing medical diagnosis, care, or treatment." *Id.* As explained above, the nonmedical technicians or engineers were not providing any medical care or treatment to Mr. Cherkala when they acted negligently. The same is true for the administrators who failed to replace the heater-cooler or train and supervise their staff. Moreover, the technicians, engineers, and administrators are not "caregivers," and were not acting as such when they proximately caused Mr. Cherkala's injuries, according to the allegations of the Complaint. CCF's negligent acts had nothing to do with Mr. Cherkala; it simply failed to maintain its heater-cooler devices. Therefore, this subsection does not apply, and the claim is not a medical claim.

IV. ALTERNATIVELY, GOOD CAUSE EXISTS TO EXTEND PLAINTIFFS' TIME TO PROVIDE AN AFFIDAVIT OF MERIT

If an affidavit of merit is required in relation to Plaintiffs' claims against CCF (it isn't, as explained above), the Court should grant Plaintiffs additional time to obtain one, as authorized under Civ.R. 10(D)(2)(b), because good cause exists.

Civ.R. 10(D)(2)(b) states that:

"The plaintiff may file a motion to extend the period of time to file an affidavit of merit. The motion shall be filed by the plaintiff with the complaint. For good cause shown and in accordance with division (c) of this rule, the court shall grant the plaintiff a reasonable period of time to file an affidavit of merit, not to exceed ninety days, except the time may be extended beyond ninety days if the court determines that a

defendant or non-party has failed to cooperate with discovery or that other circumstances warrant extension.”

In determining whether good cause exists, the Court should analyze certain factors, which include:

- (i) “A description of any information necessary in order to obtain an affidavit of merit;
- (ii) Whether the information is in the possession or control of a defendant or third party;
- (iii) The scope and type of discovery necessary to obtain the information;
- (iv) What efforts, if any, were taken to obtain the information;
- (v) Any other facts or circumstances relevant the ability of the plaintiff to obtain an affidavit of merit.”

Civ.R. 10(D)(2)(c).

All of those factors weigh in favor of granting this Motion and extending the period in which to file an affidavit of merit until such time as facts are discovered that show Plaintiffs’ claims are, in fact, medical claims.

First, the information necessary to obtain an affidavit of merit would include documents and testimony indicating CCF’s efforts, or lack thereof, to clean, disinfect, and otherwise maintain the heater-cooler devices. As it stands now, Plaintiffs have no documentary or other evidence upon which an expert could rely that shows what CCF did or did not do in that regard, and therefore cannot obtain an affidavit of merit that comports with Evid.R. 702.

Second, the information Plaintiffs need is in the possession or control of CCF. Critically, this information consists of “non-medical-record materials,” as CCF pointed out in its email to Plaintiffs’ counsel. **Exhibit 4**. As such, Mr. Cherkala has no independent right to receive that information, as he would if it were contained within his medical

records. CCF controls this information, and has not produced it, despite repeated requests.

Third, the scope of discovery necessary to obtain that information would include requests for production, interrogatories, and the deposition of a corporate representative pursuant to Civ.R. 30(B)(5).

Fourth, Plaintiffs have diligently sought the information required to obtain the affidavit of merit, but CCF has refused to produce it. As noted above, Plaintiffs sent a subpoena in connection with the MDL pending in the Middle District of Pennsylvania, but CCF would not produce documents relating to the maintenance, cleaning, and disinfection of the heater-cooler, as well as its policies, procedures, and protocols pertaining to the same, among others. Plaintiffs' counsel was unsuccessful in his multiple attempts to gain CCF's compliance with the requests in the subpoena.

Last, the circumstances present here establish good cause to grant this Motion: as set forth above, it is not at all clear that Plaintiffs' claims are medical claims. Discovery would be required to make that determination. Plaintiffs should not have to spend the money to retain an expert to provide an affidavit of merit at this stage given that it appears one is not required. Therefore, good cause exists to grant Plaintiffs additional time to submit an affidavit of merit. Specifically, Plaintiffs should not be required to submit an affidavit of merit until the facts demonstrate that this case does allege medical claims under R.C. 2305.113.

V. CONCLUSION

As demonstrated above, Plaintiffs did not allege wrongful conduct arising from any medical diagnosis, care, or treatment Mr. Cherkala received, as required by

R.C. 2305.113. Nor have they sued any caregivers for wrongful conduct in providing medical care. As such, an affidavit of merit is not required. In the alternative, however, Plaintiffs request an extension of time to obtain an affidavit of merit. Good cause exists to extend the period to file an affidavit of merit until such time as the facts demonstrate Plaintiffs' claims are medical claims.

Respectfully submitted,

/s/ Dennis R. Lansdowne

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AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Brian Cherkala, et al.

Plaintiff

v.

LivaNova PLC, et al.

Defendant

Civil Action No. 1:20 cv 1938

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To:

The Cleveland Clinic Foundation

(Name of person to whom this subpoena is directed)

☒ **Production:** YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Duces Tecum

Place: Spangenberg Shibley & Liber
1001 Lakeside Avenue East, Suite 1700
Cleveland, Ohio 44114

Date and Time:

October 6, 2020 at 10:00 a.m.**

**In lieu of personal appearance you may mail the requested documents on or before October 6, 2020 to SSL.

☐ **Inspection of Premises:** YOU ARE COMMANDED to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:

Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 9/15/2020

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party) Brian Cherkala, et al.

, who issues or requests this subpoena, are:
Dennis R. Lansdowne, William Hawal and Michael P. Lewis - Spangenberg Shibley & Liber

1001 Lakeside Avenue East, Suite 1700, Cleveland, Ohio 44114; Phone: 216-696-3232

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

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EXHIBIT 1

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE*(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)*I received this subpoena for *(name of individual and title, if any)* _____on *(date)* _____.☒ I served the subpoena by delivering a copy to the named person as follows:

Via certified mail; return receipt requested _____

_____ on *(date)* 9/15/2020 _____; or _____☐ I returned the subpoena unexecuted because: _____

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of \$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date:

9/15/2020


Dennis Lansdowne, Esq. _____

Printed name and title

Spangenberg Shibley & Liber
1001 Lakeside Avenue East, Suite 1700
Cleveland, Ohio 44114

Server's address

Additional information regarding attempted service, etc.: _____

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)**(c) Place of Compliance.**

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
 - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) *Contempt.*

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

DUCES TECUM

1. **"Document"** means any type or kind of written, typewritten, transcribed, printed, electronic, digital, or recorded material, including, but not limited to, notes, memoranda, letters, videotapes, recordings, transcripts, statements, papers, files, tapes, affidavits, forms, data, printouts, reports, contracts, communications, correspondence, emails, email message printouts, information retrievable from a computer, computer data, recorded voicemail messages or conversations, diagrams, photographs, or any other writings of any kind.

2. **"You," "Your," and "Yours"** means the Cleveland Clinic Foundation, including any individual person (whether living or deceased), partnership, firm, corporation, association, joint venture, or other entity acting on its behalf or at its direction, including any agents, representatives, employees, and attorneys, upon whom these document requests were propounded.

3. **"Identify" or "Identifying,"** means to set forth, portray, and/or explain in words.

- 1) All **documents** which relate to the Cleveland Clinic Foundation's (CCF) purchase of the Stockert 3T heater-cooler device utilized during Brian Cherkala's surgery on August 28, 2017.
- 2) All written communications by and between **you** and any LivaNova entity, Sorin Group Deutschland GMBH, or any related business entities concerning Stockert 3T heater-cooler devices up until the present.
- 3) All **documents** which **identify** all cleaning, disinfection, maintenance, or service performed on the Stockert 3T heater-cooler device used during Brian Cherkala's surgery on August 28, 2017.
- 4) All **documents** which **identify** any training, information, education, and/or certification provided to **your** employees by any LivaNova entity, Sorin Group Deutschland GMBH, or any related business entities concerning the use, cleaning, disinfection, maintenance, or servicing of Stockert 3T heater-cooler devices.
- 5) All **documents** that **identify** or relate to **your** policies, procedures, and protocols regarding the storage, use, cleaning, disinfection, maintenance, or servicing of Stockert 3T heater-cooler devices up until the present.
- 6) All **documents** which contain or refer to communications by and between **you** and any LivaNova entity, Sorin Group Deutschland GMBH, or any related business entities concerning nontuberculous mycobacterium (NTM) infections or their prevention.

- 7) All communications received from the United States Food and Drug Administration (FDA) regarding the risk of cardiac surgery patients developing NTM infections from circulatory system devices and/or heater-cooler devices.
- 8) All medical device reports (MDRs) submitted by **you** to the FDA relating to Brian Cherkala's M. chimaera infection.
- 9) All MDRs submitted by **you** to the FDA relating to any NTM infection following cardiac surgery, with patient names redacted.
- 10) All **documents** which **identify** or refer to any modifications to Stockert 3T heater-cooler devices owned by **you**, including replacement of PVC tubing.
- 11) All **documents** which relate or refer to inspection and/or testing of the Stockert 3T heater-cooler device used during Brian Cherkala's cardiac surgery on August 28, 2017 for the presence of any NTM.
- 12) All **documents** which relate or refer to any genetic analysis or whole genome sequencing of bacteria isolated from blood or tissue samples obtained from Brian Cherkala.
- 13) All communications by and between **you** and any LivaNova entity, Sorin Group Deutschland GMBH, or any related business entities and their representatives concerning Brian Cherkala.
- 14) Any **documents** referring or relating to any investigation into Brian Cherkala's heart valve surgery performed on August 28, 2017 and/or his M. Chimaera infection.
- 15) If **you** withhold production of any **documents** based upon the assertion of any privilege, please produce a privilege log identifying the title, author, and date of each **document** withheld, as well as the specific privilege that applies to each such **document**.



Cheryl O'Brien, Esq.
Senior Counsel
Direct Dial: (216) 448-0199
Fax: (216) 448-0204

October 8, 2020

VIA OVERNIGHT MAIL

William Hawal, Esq.
Spangenberg Shibley & Liber
1001 Lakeside Avenue East, Suite 1700
Cleveland, Ohio 44114

Re: *Brian Cherkala, et al. v. LivaNova PLC, et al.*
U.S. District Court, Northern District of Ohio, Case No. 1:20-cv-1938
Subpoena issued to The Cleveland Clinic Foundation

Dear Bill:

With regard to your subpoena *duces tecum* dated September 15, 2020 ("subpoena") and issued to non-party The Cleveland Clinic Foundation ("CCF"), we will be producing to you documents bates labeled **Cherkala CCF 000001 through 001036**.

These documents are being produced to you in good faith and specifically subject to the terms of the attached Protective Order. CCF designates all of these documents as Protected Documents under this Protective Order. Please sign and return a copy of the Protective Order to me prior to opening any of the documents. Once you have returned the signed Protective Order, we will provide you with the Password to open the disk. Please note that the Protective Order provides, among other terms, that you require anybody else to sign this Protective Order before you share any of the Protected Documents documents with them.

In producing these documents, CCF does not waive any objections to the subpoena. CCF maintains the following objections: The subpoena contains requests that are vague, overly broad, irrelevant and not proportional to the needs of the case in violation of FRCP 26(b). The subpoena imposes undue burden and expense in violation of FRCP 45(d). The subpoena does not comply with FRCP 45(a)(2) because it is not issued by the court where this matter is pending. The subpoena requests information protected by the quality assurance and peer review privileges set forth in Ohio statutory law and Ohio/federal case law, the attorney-client privilege,

Law Department
3050 Science Park Drive/AC321
Beachwood, OH 44122

Phone: 216-448-0200
Fax: 216-448-0201

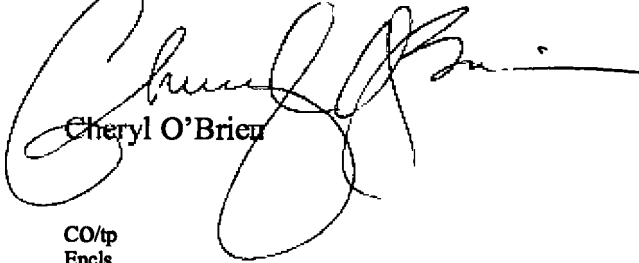
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EXHIBIT 2

the Health Insurance Portability & Accountability Act (HIPAA) and accompanying Ohio medical privacy laws, and the self-critical analysis privilege. Finally, the subpoena requests information that is otherwise confidential, including pursuant to federal and state statutes, proprietary, and readily available from other sources, including other parties in this case and public records.

By producing these documents in good faith, CCF does not waive any of these objections. Thank you for your agreement to these terms.

Very truly yours,



Cheryl O'Brien

CO/tp
Encls.

SPANGENBERG SHIBLEY & LIBER TRIAL LAWYERS

 COMMITMENT. INTEGRITY. RESULTS.

PETER H. WEINBERGER, OF COUNSEL
WILLIAM HAWAL
PETER J. BRODHEAD, OF COUNSEL
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STUART E. SCOTT
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JEREMY A. TOR, LICENSED IN NY, OH
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MICHAEL P. LEWIS, LICENSED IN CA, OH
KEVIN C. HULICK
EMILY DAVIS

CRAIG SPANGENBERG
(1914-1998)

NORMAN W. SHIBLEY
(1921-1992)

JOHN D. LIBER
(1938-2013)

March 5, 2021

Via Email: obrienc@ccf.org

Cheryl O'Brien, Esq.
Cleveland Clinic Foundation
Law Department
3050 Science Park Drive | AC321
Beachwood, OH 44122

In Re: Brian Cherkala, et al vs. LivaNova PLC, et al
U.S. District Court, Northern District of Ohio
Case No. 1:20-cv-1938

Dear Cheryl:

I hope you and your family are safe and well. I write to you with respect to Brian Cherkala and your response to our subpoena in this case. You may know that our case has been transferred to the multi-district litigation in the Middle District of Pennsylvania.

In going through the documents the Clinic has produced, we note many categories requested in which no documents have been produced. I will go through the list below.

1. All **documents** which relate to the Cleveland Clinic Foundation's (CCF) purchase of the Stocker 3T heater-cooler device utilized during Brian Cherkala's surgery on August 28, 2017.

No documents produced. Please have a records custodian confirm no documents exist responsive to this request.

EXHIBIT 3

4. All **documents** which **identify** any training, information, education, and/or certification provided to **your** employees by any LivaNova entity, Sorin Group Deutschland GMGH, or any related business entities concerning the use, cleaning, disinfection, maintenance, or servicing of Stockert #T heater-cooler devices.

The documents produced have some communications relating to instruction for use but no evidence of any actual training provided to Clinic employees by any LivaNova entity. Please advise if any exist and have a records custodian confirm no other documents exist responsive to this request.

5. All **documents** that **identify** or relate to **your** policies, procedures, and protocols regarding the storage, use, cleaning, disinfection, maintenance, or servicing of Stockert 3T heater-cooler devices up until the present.

No documents have been produced. I find it hard to believe that the Clinic does not have documents responsive to this request, particularly considering the issues that arose with the Stockert 3T units. These documents may be very important in our claims against LivaNova as LivaNova may well claim the Clinic is partly or wholly responsible for Brian's infection. Please provide or have a records custodian confirm no documents exist.

8. All medical device reports (MDRs) submitted by **you** to the FDA relating to Brian Cherkala's M. chimaera infection.

Please have a records custodian confirm no documents exist responsive to this request.

9. All MDRs submitted by **you** to the FDA relating to any NTM infection following cardiac surgery, with patient names redacted.

Please have a records custodian confirm no documents exist responsive to this request.

10. All **documents** which relate or refer to inspection and/or testing of the Stockert 3T heater-cooler device used during Brian Cherkala's cardiac surgery on August 28, 2017 for the presence of any NTM.

Please have a records custodian confirm no documents exist responsive to this request.

13. All communications by and between **you** and any LivaNova entity, Sorin Group Deutschland GMBH, or any related business entities and their respentatives concerning Brian Cherkala.

Please have a records custodian confirm no documents exist responsive to this request.

14. Any **documents** referring or relating to any investigation into Brian Cherkala's heart valve surgery performed on August 28, 2017 and/or his M. Chimaera infection.

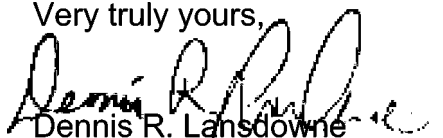
Please have a records custodian confirm no documents exist responsive to this request.

15. If **you** withhold production of any **documents** based upon the assertion of any privilege, please produce a privilege log identifying the title, author, and date of each **document** withheld, as well as the specific privilege that applies to each such **document**.

Again, we request a privilege log for any documents withheld.

If you have any questions or concerns, please contact me. We are under deadlines in the MDL, so I would appreciate your response at your earliest convenience.

Very truly yours,


Dennis R. Lansdowne
dlansdowne@spanglaw.com

DRL/lm

Michael P. Lewis

From: O'Brien, Cheryl <OBRIENC@ccf.org>
Sent: Monday, May 24, 2021 2:13 PM
To: Dennis Lansdowne; Leanne Melnick
Cc: William Hawal; Tisha Broad; Michael P. Lewis
Subject: RE: Brian Cherkala, et al. v. LivaNova PLC, et al

Dennis, thanks for your email of May 18 and we appreciate your patience. We worked very hard to gather for you and Bill the requested CCF records late last year, including a long list of non-medical-record materials regarding the 3T heater-cooler as it relates to your client Mr. Cherkala, in response to the subpoena, and following a detailed search of our records. Some of the documents we located were privileged and have not been produced for that reason, but all non-privileged and responsive documents that we located pertinent to Mr. Cherkala were produced. This was a thorough and good faith response to all requests in the subpoena. It certainly should provide you with everything needed to participate in the MDL process where this case now resides, including the MDL settlement program. As to any deadlines in the MDL, our understanding is that there are none applicable to the Cherkala matter. In fact, our understanding is that discovery like this is supposed to be stayed in the MDL. We are certainly happy to continue working with you as to any categories of additional documents that you still need for the MDL. But we'd first like a clear understanding of whether discovery is stayed or not, and what specifically are the MDL deadlines to which you are referring.

Cheryl



Cleveland Clinic

Cheryl O'Brien RN JD | Senior Counsel | Law Department
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From: Dennis Lansdowne [mailto:DLansdowne@spanglaw.com]
Sent: Tuesday, May 18, 2021 10:48 AM
To: Leanne Melnick <LM@spanglaw.com>; O'Brien, Cheryl <OBRIENC@ccf.org>
Cc: William Hawal <WHawal@spanglaw.com>; Tisha Broad <TBroad@spanglaw.com>; Michael P. Lewis <mlewis@spanglaw.com>
Subject: [EXT] RE: Brian Cherkala, et al. v. LivaNova PLC, et al

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Cheryl: I have not received any response to my letter from two months ago. I know you are very busy but I need a response as I am under deadlines in the Federal case. This case has been transferred to the Multi-District Litigation In Pennsylvania and they have strict procedures. Please respond at your earliest convenience.

Thank you for your cooperation.

Dennis

Electronically Filed 08/26/2021 11:20 / MOTION / CV 21 952213 / Confirmation Nbr. 2336456

EXHIBIT 4

From: Leanne Melnick <LM@spanglaw.com>

Sent: Friday, March 05, 2021 1:21 PM

To: O'Brien, Cheryl <OBRIENC@ccf.org>

Cc: Dennis Lansdowne <DLansdowne@spanglaw.com>; William Hawal <WHawal@spanglaw.com>; Tisha Broad <TBroad@spanglaw.com>; Leanne Melnick <LM@spanglaw.com>

Subject: Brian Cherkala, et al. v. LivaNova PLC, et al

Ms. O'Brien, attached is correspondence from Dennis. Email will be the only form of transmittal.

From: Leanne Melnick <LM@spanglaw.com>

Sent: Friday, March 05, 2021 1:21 PM

To: O'Brien, Cheryl <OBRIENC@ccf.org>

Cc: Dennis Lansdowne <DLansdowne@spanglaw.com>; William Hawal <WHawal@spanglaw.com>; Tisha Broad <TBroad@spanglaw.com>; Leanne Melnick <LM@spanglaw.com>

Subject: Brian Cherkala, et al. v. LivaNova PLC, et al

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